EXHIBIT D

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO WAVE 1**	**Master File No. 2:12-MD-02327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

RULE 26 EXPERT REPORT OF DR. DIONYSIOS K. VERONIKIS GYNEMESH PS (AND PROLENE SOFT MESH)

The following report is provided pursuant to Rule 26 of the Federal Rules of Civil Procedure.

QUALIFICATIONS

I, Dionysios K. Veronikis, MD, am fellowship trained with board certification in Female Pelvic Medicine and Reconstructive Surgery as well as general OB/GYN. I received my general Board Certification in Obstetrics and Gynecology in 2000 and my Sub-specialty Board Certification in Female Pelvic Medicine and Reconstructive Surgery in 2013 (first time certification was offered). Both certifications are active until December 2016.

A copy of my current curriculum vitae is attached to this report as Exhibit A.

I am a diplomat of the American Board of Obstetrics and Gynecology (ABOG), a fellow of both the American College of Obstetricians and Gynecologists (ACOG) and the American College of Surgeons (ACS). I am a member of the American Urogynecologic Society (AUGS),

the Society of Gynecologic Surgeons (SGS), the American Association of Gynecologic Laparoscopic Surgeons (AAGL), International Urogynecological Association (IUGA) and the International Continence Society (ICS). I have been awarded the Council on Resident Education in Obstetrics and Gynecology "Teacher of the Year" by the resident staff of the Massachusetts General Hospital and the Brigham and Women's Hospital in 1997 and by the resident staff of St. John's Mercy Hospital in 2002. I won the Society of Gynecologic Surgeons First Prize Fellow Research Award in 1996 and 1997.

I received my BS in Biology and Experimental Psychology from Moravian College in Bethlehem, Pennsylvania in 1982 and graduated with an MD from the University of Patras School of Medicine and Allied Health Sciences in Patras Greece in 1988. I did my internship in General Surgery at Morristown Memorial Hospital in Morristown, New Jersey from 1990 to 1991 and my residency in Obstetrics and Gynecology from 1991 to 1994 at Baystate Medical Center in Springfield, Massachusetts. I was a fellow in Vaginal Surgery and Urogynecology at the Massachusetts General Hospital, Harvard Medical School in Boston, Massachusetts from 1994 to 1997 under the mentorship of Dr. David Nichols.

Since 1997 I have been the Chief of Gynecology and Director of Vaginal Reconstructive Surgery and Urogynecology at St. John's Mercy Medical Center in St. Louis, Missouri. In this capacity I am responsible for training the general OB/GYN residents in Vaginal Surgery and Urogynecology in the clinic, the classroom and the operating room. In 2003 I became the Program Director for the Obstetrics and Gynecology Residency Program at St. John's Mercy Medical Center.

I have been a visiting surgeon across the United States and to Europe visiting Parma, Italy; University of Liege, Belgium; Kent, England and Madrid, Spain.

My surgical practice has exclusively focused on Vaginal Reconstructive Surgery and Urogynecology since 1994 with an annual case load that I estimate exceeds 600 cases annually. I estimate that I have personally performed nearly 10,000 vaginal reconstructive surgeries for incontinence and pelvic organ prolapse and I have implanted thousands of mesh products. I have cared for women from 49 states across the United States, four Canadian Provinces and four continents.

I am extremely familiar with the injuries and problems associated with the transvaginal mesh products from the thousands of patients I have examined and treated as these women present for evaluation and treatment. I have reviewed volumes of patient's medical records that has allowed me to reliably correlate the symptoms and complications that develop from mesh placement and to develop a differential diagnosis that is consistent and supports my observations and opinions and confirms my surgical findings at the time of mesh revision/removal. I have revised/removed many mesh products for mesh complications that include but are not limited to mesh erosion, exposure, apareunia, dyspareunia, pelvic pain, and hip or leg pain. I have a vast and global experience with mesh removal, including retropubic, suprapubic, transobturator and single incision slings and anterior and posterior mesh from American Medical Systems, Boston Scientific, Ethicon, Bard, Coloplast, Caldera, Mentor and Tyco.

I have significant surgical experience encompassing the breadth and depth of vaginal reconstructive pelvic surgery including transvaginal mesh removal surgeries.

My first experience with vaginal mesh used to treat pelvic floor defects was in 1994, during my fellowship with Dr. David Nichols when I trained in Boston.

I estimate that I have personally examined, diagnosed and treated over a thousand patients with mesh complications. Currently, I devote half my surgical referral practice to treating vaginal mesh complications.

I estimate that have revised/removed over a thousand vaginal mesh products including transvaginal mesh slings and prolapse mesh (including Gynemesh PS) and in 2015 alone I surgically removed 296 mesh implants**.**

Based upon my clinical work as a vaginal surgeon, urogynecologist and pelvic floor reconstructive surgeon, I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis, and treatment of patients suffering from complications caused by pelvic mesh implants. The most common mesh related complications include vaginal mesh exposure/extrusion through the vaginal epithelium, mesh erosion into the rectum, bladder, and or urethra, acute and chronic vaginal and pelvic pain, apareunia, dyspareunia and nerve damage.

OPINIONS

All of my opinions in this report I hold to a reasonable degree of medical certainty.

1. Failure to Warn

In my own experience with explanting the Gynemesh PS product, as well as practicing urogynecology for 19 years, I have been well-acquainted with Ethicon's materials used in regards to the transvaginal mesh surgery using Gynemesh PS, including the Instructions for Use (hereafter referred to as IFU), professional education materials, and information used by the sales force.

In the medical community, it is fairly assumed that the manufacturers of products such as Gynemesh PS equip the physicians with all known information regarding that medical device

through various outlets including, but not limited to, the product's IFU, professional education materials, the company's employees, and patient brochures. This process is necessary to the surgeon's evaluation of the product and its use in his or her specific patients. If this assumption is not fulfilled, it is not possible for the surgeon to accurately evaluate risks versus benefits of the device and advise the patient on his or her specific situation. Without this, the patient cannot possibly understand what she is agreeing to in terms of the procedure – hence the informed consent in this situation would be meaningless.

Along these same lines, it is necessary for the manufacturer of the device to warn of potential adverse events and complications that can accompany the implantation of the device. However, it is not sufficient to simply warn of these adverse events. The company is also responsible for alerting the physicians to the frequency and severity of the possible complications, as well as the potential duration of such complications. If known information regarding elements of the product and/or procedure that increase the likelihood and severity of an adverse event is withheld from the implanting physician, the company has misled that physician and, in turn, his or her patient. In regards to Gynemesh PS, the IFU claims the risks of this device "are those typically associated with surgically implantable materials". This verbiage is deficient and does not accurately represent the actual frequency and severity of said complications, and, therefore, misinforms the physicians using the product.

a. Deficiencies with Gynemesh PS IFU

The IFU for Gynemesh PS contains claims that the material used in the mesh construction of this product is "nonreactive", citing that animal studies "show that Prolene mesh elicits a minimum to slight foreign body reaction, which is transient…" However, numerous Ethicon corporate documents contradict this, demonstrating that they had knowledge that the

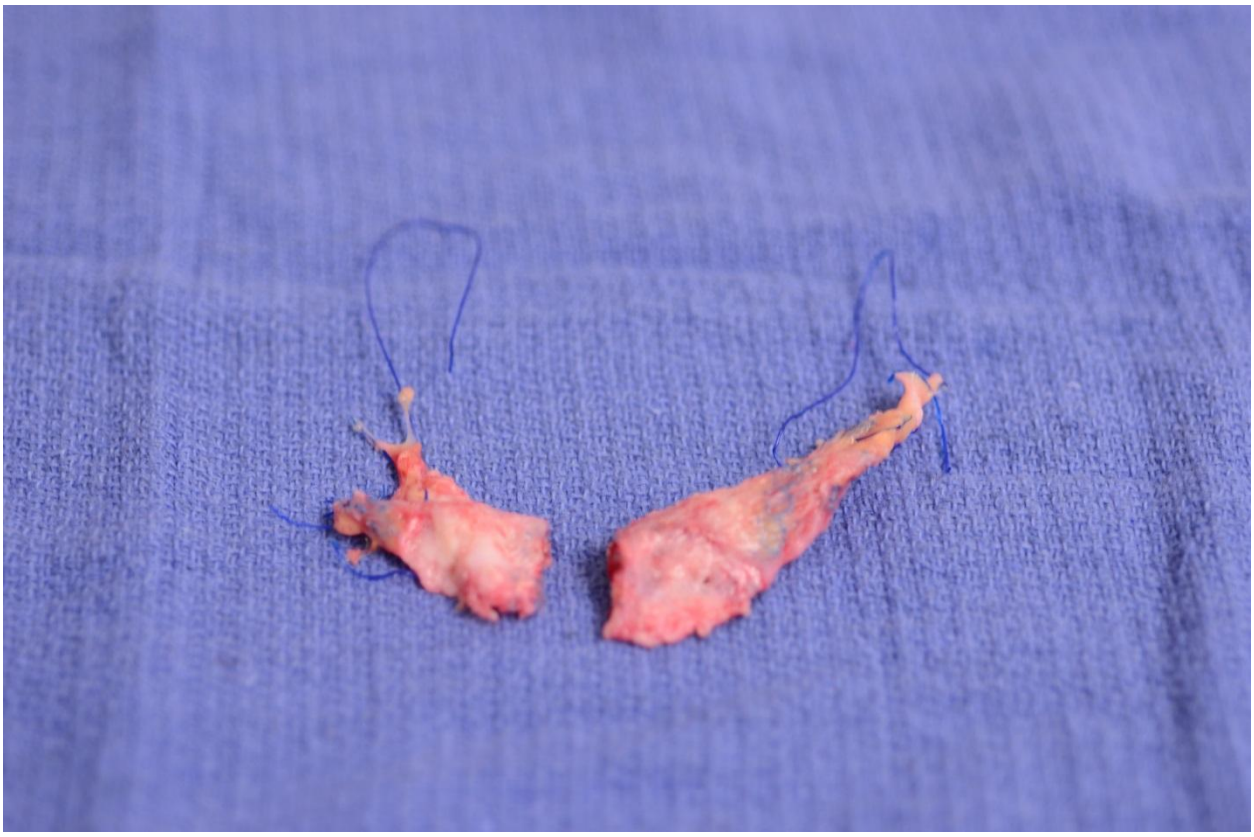
mesh material used in construction of Gynemesh PS elicits an "excessive" and "chronic" foreign body reaction and "intense" and "chronic" inflammation.[1] For example, an internal email from 2008 states, "Polypropylene creates an intense inflammatory response that results in rapid and dense incorporation into the surrounding tissue. The excessive inflammatory reaction caused by heavyweight meshes tends to form a scar plate around the prosthetic that results in a firm and contracted mesh"[2]. This is consistent with my observations from personal experience with explanting this Gynemesh PS mesh from patients.

Furthermore, the IFU claims that "[t]he material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes" despite additional Ethicon documents discussing polypropylene's degradation in vivo and the knowledge of this reaction prior to development of Gynemesh PS for use in pelvic floor repair.[3] For example, in an internal e-mail chain discussing literature on polypropylene degradation, it is stated that they "know from literature that polyester and even polypropylene tend to alter over time in the body" and they "proposed for several new product developments...to use PVDF or PRONOVA as a more stable filament, however Senior Management decided to go ahead with PP as a standard"[4].

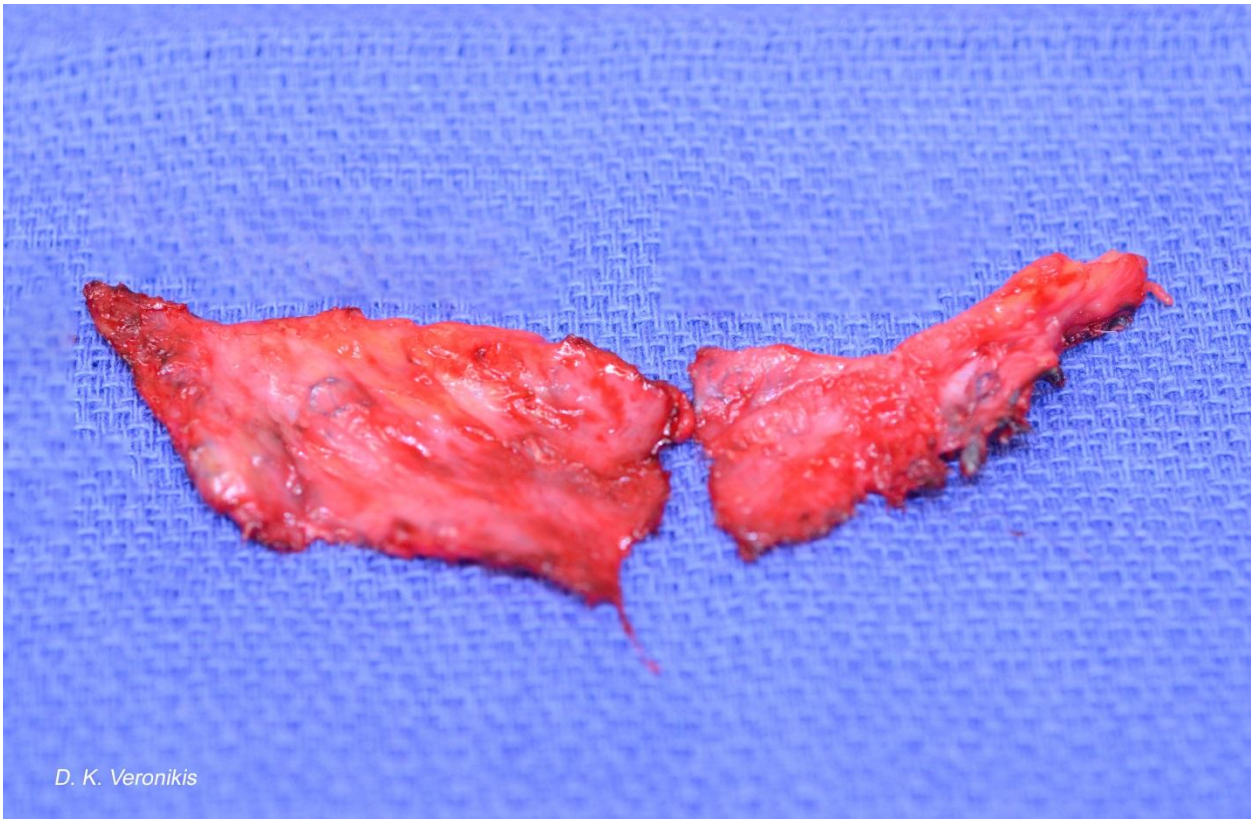
At this point, it should be noted that my criticisms of Gynemesh PS are equally applicable to Ethicon's Prolene Soft mesh as used in the female pelvis, as they are the identical mesh products.

The Gynemesh PS IFU also claims that this mesh will "retain its strength indefinitely in clinical use," "has excellent strength," and "remains soft and pliable and wound healing is not noticeably impaired". These statements are in direct contradiction to Ethicon documents such as an internal memo from 2001 that list disadvantages of the Prolene Soft mesh material that is used in Gynemesh PS. The memo states, that the "VOC", or Voice of Customer (the physicians),

acknowledge Prolene Soft is "too stiff for use in vaginal tissues" [5]. Numerous other Ethicon documents discuss their knowledge of the material being stiff and inflexible, as well as over-engineered, too strong and not designed for the pelvic floor.[6] Again, these descriptions are consistent with my own personal observations of explanting Gynemesh PS in my practice.



Above is explanted Gynemesh PS (Source DK Veronikis, MD).



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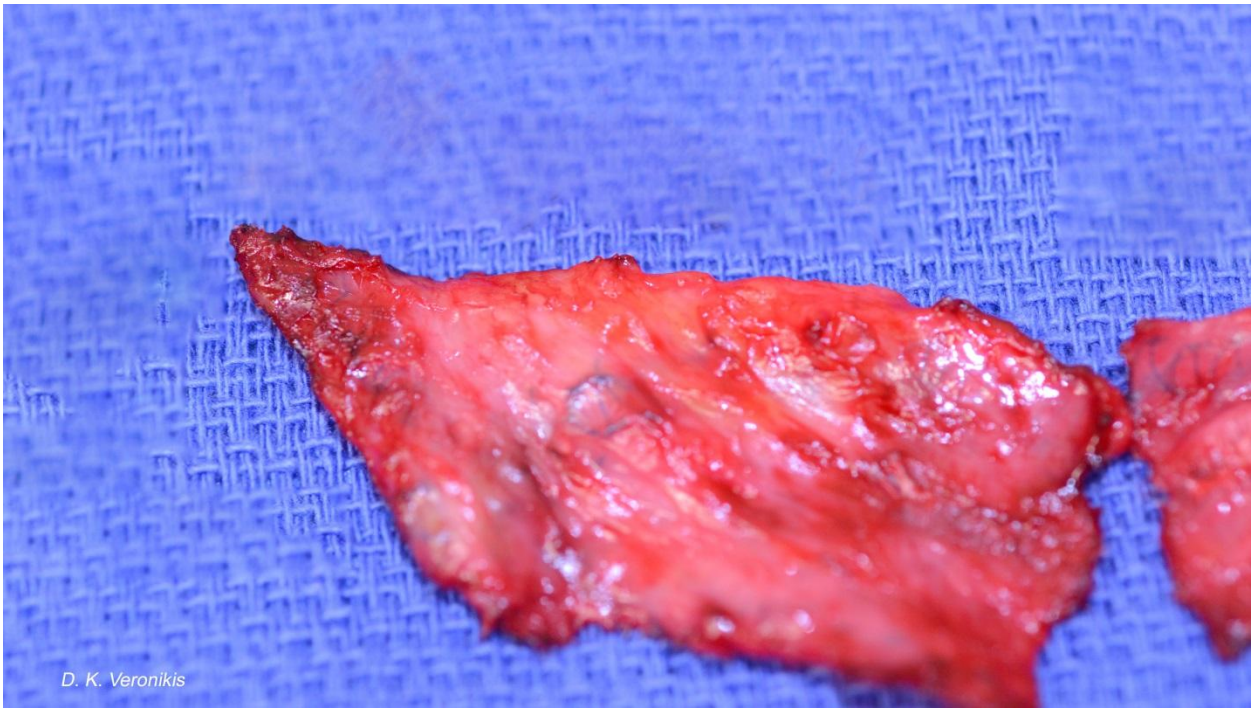

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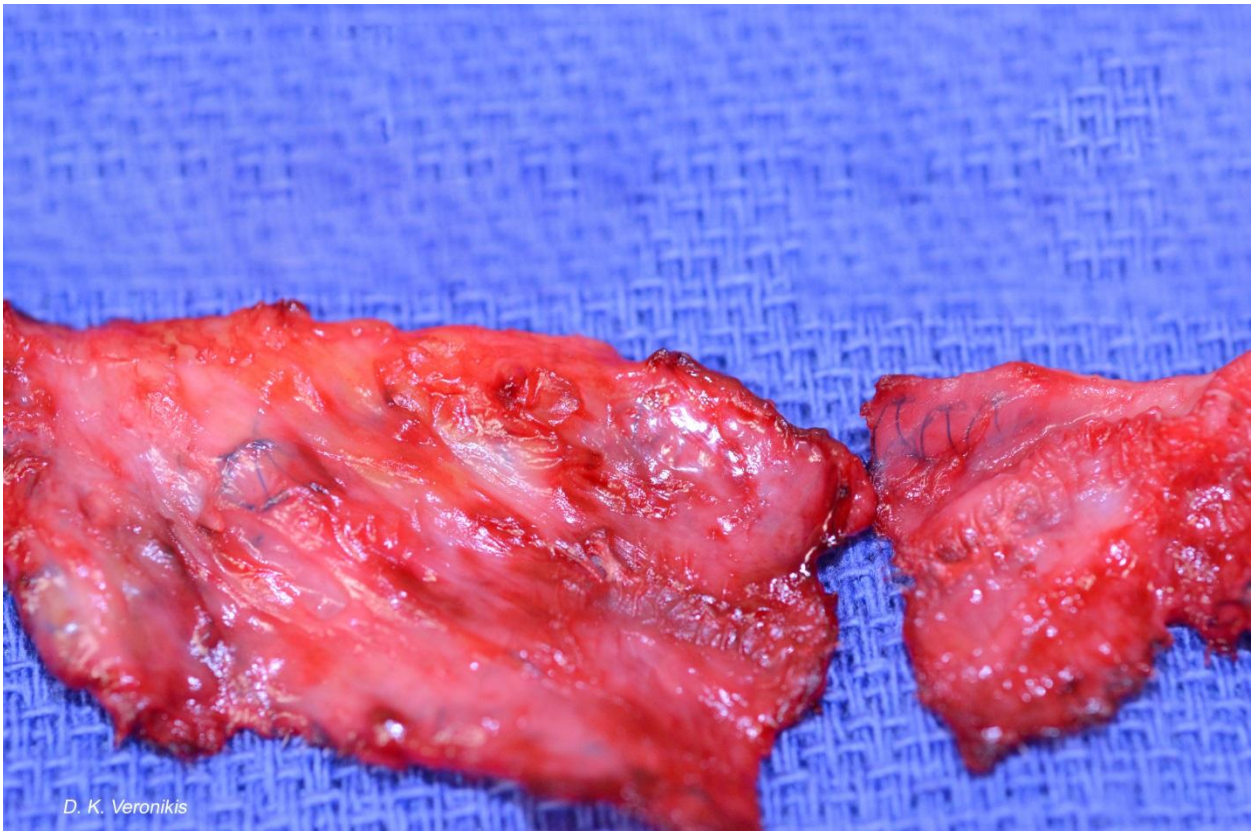


Above is explanted Gynemesh PS (Source DK Veronikis, MD).

Lastly, the Gynemesh PS IFU claims that "[t]he bi-directional elastic property [of the mesh] allows adaptation to various stresses encountered in the body", which in this case is the female pelvis and the pelvic organs. However, Ethicon carried out no tests or studies to back this statement up and therefore, this claim lacks sufficient evidence, which is yet another example of a manner in which Ethicon's IFU for this product was intentionally misleading.

b. Exclusion of Instructions/Warnings for Gynemesh PS

Ethicon did not inform physicians that Gynemesh PS was "better suited" for patients with severe Pelvic Organ Prolapse (POP). Their knowledge from a clinical study conducted by Michel Cosson, a developer of the transvaginal mesh use of Gynemesh PS, included information

that patients with Grade IV prolapse or worse were the most appropriate candidates for this surgery. No instruction or constraint was given regarding the severity of a patient's prolapse in regards to Gynemesh PS.[7]

Ethicon failed to warn physicians and patients about the risks associated with the Gynemesh PS, and/or else failed to properly warn of the frequency, severity and duration of the risks that were disclosed. In my opinion, the omission of instructions or warning as set forth below rendered the Gynemesh PS not reasonably safe for transvaginal POP repair.

Ethicon provided no warning that the polypropylene used in the Gynemesh PS causes intense, chronic and excessive inflammation and foreign body reaction.

Ethicon did not warn of the foreign body reaction that its employees knew occurs with the implantation of this product. As previously mentioned, polypropylene elicits an intense, chronic inflammation. Additionally, no warning was provided regarding the inadequate pore size of the Prolene Soft mesh Gynemesh PS which impacts this foreign body response. This mesh contains pore sizes much smaller than the necessary 1mm.[8]. In addition, an internal e-mail regarding the Prolene Soft pore size stated that "pore size measurements vary if the mesh is pulled even lightly in any direction"[9]. Ethicon did not warn doctors that the pore size of the Gynemesh PS will decrease with implantation pressure.

Ethicon did not warn of the frequency and severity of shrinkage associated with the mesh and failed to inform of risks and complications that result from the shrinkage.[10] Ethicon documents show 20-40% contraction with the mesh products. An internal email from 2004 acknowledges that Ethicon's consulting physicians' "main concern is now the shrinkage of the mesh which may lead to pain, dyspareunia…Indeed now that [the physicians] have tremendously improved the technique and lowered the erosion rate what needs to be improved is the shrinkage

of the mesh (in this case Gynemesh soft)"[11]. Further acknowledgement of the need to improve the Prolene Soft/Gynemesh PS is noted in a 2005 e-mail from an Ethicon engineer. He states, "In pelvic floor repair even with the [Prolene Soft Mesh], we have seen some scar contracture which translates into procedural complications… [S]urgeons who are our consultants on the ProLift product are asking for a mesh which is better than [Prolene Soft Mesh] in this area… The surgeons attribute these conditions [recurrence of prolapse, pain, stiffness, erosion and discomfort during sex] to scar contracture"[12]. More evidence of the pain caused by this contracture is seen in a clinical study of Gynemesh PS in 2007 which found 19.6% "painful mesh shrinkage"[13].

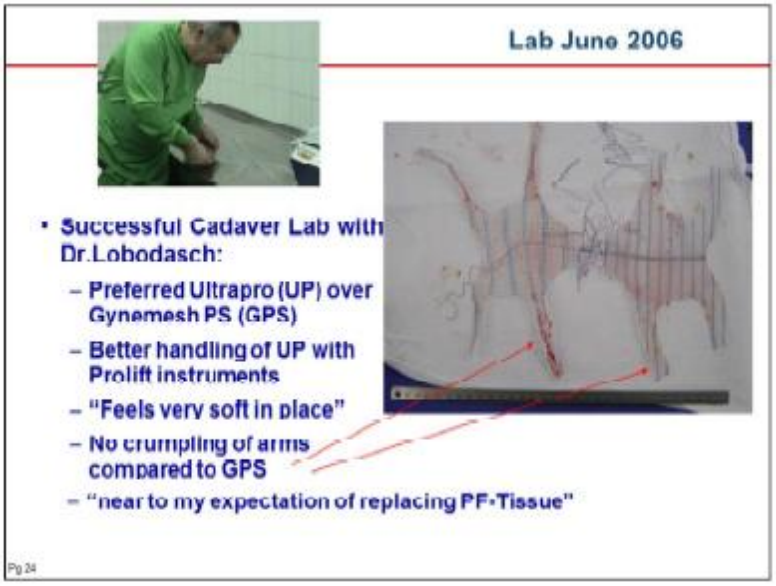
Ethicon did not provide any warning regarding pain, especially not severe and chronic or lifelong pain. The numerous types of pain which could potentially result from transvaginal mesh implantation were also not addressed or communicated to physicians or patients.

In regards to the dyspareunia experienced by patients, Ethicon's European Medical Director encouraged Ethicon in 2005 to add a warning to the Prolift IFU that stated: "WARNING: Early clinical experience has shown that the use of mesh through a vaginal approach can occasionally/uncommonly lead to complications such as vaginal erosion and retraction which can result in anatomical distortion of the vaginal cavity that can interfere with sexual intercourse. Clinical data suggest the risk of such a complication is increased in case of associated hysterectomy. This must be taken in consideration when the procedure is planned in a sexually active woman." Despite Gynemesh PS being the mesh material that comprised the Prolift device, no warning of the known risks of vaginal and anatomical distortion and hindrance to sexual intercourse nor cautioning to avoid use of Gynemesh PS for pelvic floor repair in sexually active women was adequately conveyed to the implanting physicians.

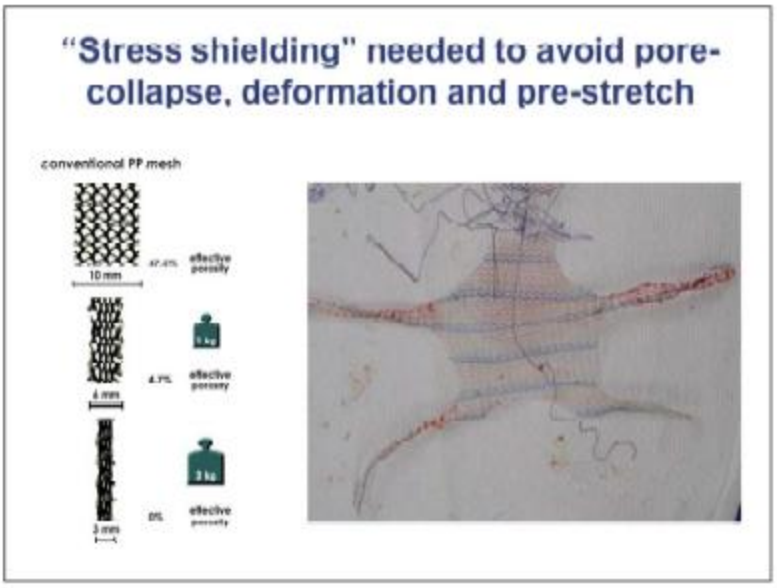
Ethicon did not warn of the possibility of damage to the nerves with Gynemesh PS, involving phenomena such as nerve entrapment, nerve tethering, and nerve severing.[14] In an Ethicon PowerPoint from 2010, a slide discusses studies of explanted meshes in which nerve fibers and fascicles were found in the interface of the mesh. It states, "The nerve structures are irritated by the inflammation and cause sensation of pain [citing 2005 article]"[15]. Information to this effect was not provided to physicians by Ethicon.

In terms of the procedure, Ethicon had knowledge that the arms on the Prolift device, which were comprised of Gynemesh PS, deform and "crumple" during implantation.[16]

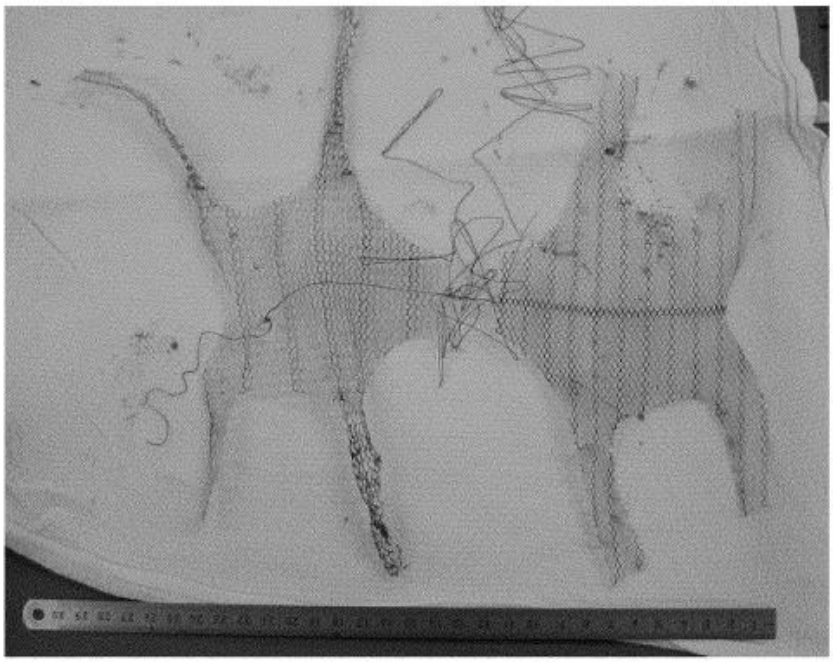
ETH.MESH.05237919 (3/25/09 internal PowerPoint), p. 24, showing explanted Prolift mesh from June 2006 cadaver lab:

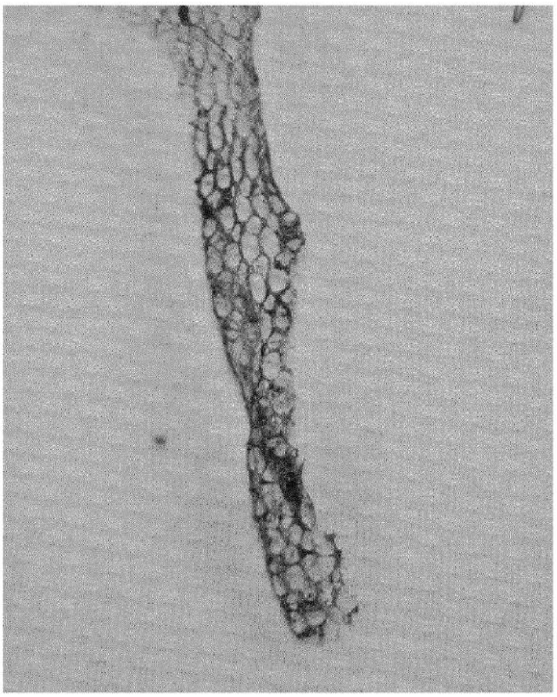


ETH.MESH.02227282 (11/14/09 internal PowerPoint), Slide 6 – Photograph of explanted Prolift mesh showing deformation of arms:

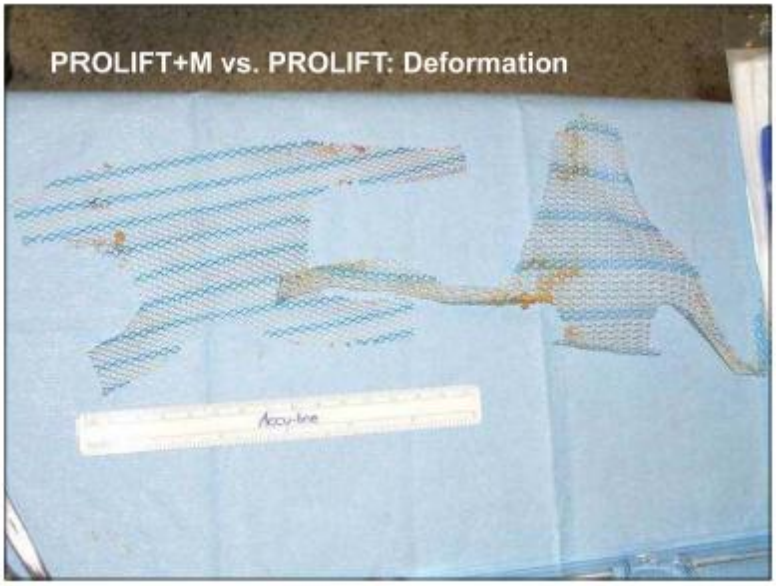


ETH.MESH.05454207 (8/1/06 internal e-mail with photos from cadaver lab showing deformation ("crumpling") of Gynemesh PS arms):





ETH.MESH.05237872 (5/27/11 PowerPoint – photos of Prolift with deformed arms):



Despite visual evidence from the Cadaver Lab in 2006 shown above and Ethicon documents regarding the research and design of the mesh which discussed these known issues, Ethicon withheld crucial information regarding this risk from physicians.

Finally, Ethicon did not advise the physicians of potentially permanent complications that they knew the Gynemesh PS could cause. In a PowerPoint presentation from 2008, Ethicon's Medical Director Piet Hinoul says to "Inform! Mesh is permanent. Some complications may require additional surgery that may or may not correct the complication. Potential for serious complications and their effect on quality of life: pain during intercourse, scarring, narrowing of the vaginal wall."[17] These risks were never conveyed nor was any warning regarding removal of this mesh product being a possibility. After implantation, removal of the totality of the Gynemesh PS is challenging. Whether explanting parts or attempting to remove the whole, a removal surgery requires a highly skilled surgeon which only a few are truly equipped and skilled to perform. No IFU for Gynemesh PS expresses the possibility of continuous complications resulting from the implant such as multiple surgeries or the potentially impossible removal of the mesh due to such complications.

Despite information available to Ethicon in the form of clinical study results that demonstrated a lack of efficacy and a lack of safety for the Gynemesh PS used transvaginally for prolapse repair,[18] Ethicon failed to adequately convey any warning to doctors regarding these adverse study results. In this regard, see the discussion in Part 3 below. Given the failure rate in Ethicon's own study, surgeons should have been warned of the lack of efficacy.

c. Due to all of this crucial information that Ethicon withheld from implanting physicians, I am of the opinion that Gynemesh PS should not have been considered reasonably safe for repair of pelvic organ prolapse. Doctors, including myself, depend on medical product

and device IFUs to assess the best and safest possible treatment options for their patients. If Ethicon discovered important information regarding their product after its launch, the IFU for that product should be updated to include all relevant and known information. This process is imperative to keep physicians informed about the products they are using. The company is obliged to the physician and the patient in this regard. Without all relevant information, the physician is unable to accurately make an informed decision regarding the risks versus benefits and counsel his or her patient in a manner that would result in true informed consent of the patient. However, while revisions were made to the Gynemesh PS IFU over the years after its launch, the information I've discussed was not included in said revisions.

Additionally, the contraindications section of a product's IFU should include all portions of a population that cannot be implanted with that product safely. The Gynemesh PS Contraindications section of the IFU identifies infants, children, pregnant women, and women who may become pregnant as portions of the population in which the Gynemesh PS should not be implanted. This list suggests that those who do not fall into this category are acceptable patients for implantation of this product. If there is in fact a portion of the population not listed which would be subject to additional risks, and the manufacturer does not disclose that information, it is needlessly endangering those patients.

2. Defective Design

After studying the design of transvaginal mesh and the implant device in which the mesh is used, as well as personally explanting hundreds of mesh implants, I would consider myself well-educated on the design of these products. Discussions at medical society meetings regarding this design with representatives of companies who manufacture these products and fellow urogynecologists have yielded a wealth of knowledge on the material. As I've previously

stated, physicians fairly assume that a manufacturer of a medical implant product will themselves weigh all known risks against the benefits regarding the safety and efficacy of the product, as well as provide that information in its entirety to the physician customers.

It is important to remember in this situation that pelvic organ prolapse is not a life-threatening condition. When examining the risks versus benefits, it is imperative to keep in mind that a transvaginal mesh implant is intended to be permanent. However, it has been revealed that the potential risks of a transvaginal mesh implant of Gynemesh PS are known to be severe and induce lifelong negative consequences. An Ethicon PowerPoint from 2003 states, "Pelvic organ prolapse is a functional disorder, not a life threatening disease. 1. Abstention is always a possibility. 2. Whatever the treatment, it must not create serious complications".[19] Therefore, any benefits of treating pelvic organ prolapse with this mesh do not outweigh the inherent risks of the product.

Gynemesh PS is a polypropylene based mesh also known as Prolene Soft. There are several known problems with this material. For example, the pore size is not sufficiently large to facilitate the appropriate tissue ingrowth that is necessary to prevent excessive fibrotic bridging between pores. The complications that arise from severe fibrotic bridging can be described as a sort of chain reaction. The intense scarification caused by fibrosis results in mesh contraction, which in turn leads to mesh erosion, vaginal deformation, damage to nerves and, consequently, chronic pain. It is known and acknowledged by Ethicon that pore size must be 1mm or greater to potential prevent this reaction."[20] It is important to note that this pore size is necessary to remain at 1mm or greater after implantation and under physiologic stress in vivo, and "Mesh pore size varies under the impact an applied load"[21]. Another issue with the polypropylene construction of Gynemesh PS is its potential to elicit an intense foreign body reaction and chronic inflammation.

Despite having safer, equally as effective, alternative materials[22] Ethicon used the polypropylene mesh that is known to contract and degrade in the human body.

Further, there is a biological mismatch between the pelvic floor tissues and the Prolene Soft mesh. Gynemesh PS was not specifically created for use in the pelvic floor but was designed for use in hernia repair. Ethicon was aware of the differences between the pelvic floor and the abdominal wall and discussed the need to further investigate this disparity. For example, in an Ethicon Meeting in 2007, the "need to learn more about special anatomic features in vaginal region" was stated, as well as the fact that the vagina is completely different from the abdominal wall[23]. However, Ethicon never took into consideration or ignored the properties of the female pelvic floor and the differences between it and the abdominal wall prior to the launch of Gynemesh PS in the use of pelvic floor repair for pelvic organ prolapse.[24] Even in 2011, Ethicon stated in an internal memo regarding the biomechanical considerations for pelvic floor mesh design that "The ideal mesh for prolapse repair which mimics precisely the biomechanical needs of the pelvic floor region has not been developed…. Pain and discomfort can result from stiff mesh that were originally designed for hernia surgery and 'over-engineered' to exceed the burst strength of the abdominal wall at the cost of losing compliance"[25]. Ethicon failed to determine the consequences of using a mesh designed for the abdominal wall in the pelvic floor prior to marketing Gynemesh PS for use transvaginally.

In addition to the concerns with the construction of the mesh material, the design of the Gynemesh PS and the TVM procedure introduced too much foreign material for the area in which it was implanted. Because of the mismatch in size, the mesh shifts, curls, or folds with pelvic pressure and day-to-day movement and activity of patient.

Similarly, it is known that the vagina needs much more elasticity than the abdominal wall. Therefore, it is important for the mesh implant to be elastic and soft to perform its function in the pelvic floor. However, the polypropylene mesh is stiff and inflexible which, as I previously mentioned, had been made known to Ethicon early on. This stiff and inflexible mesh does not allow for normal movement of vaginal tissues, but rather the mesh is rigid and restrictive to these vaginal tissues. Hernia mesh literature for this material even stated that mesh can be the cause of "considerable restriction of abdominal wall mobility" and "rigidity and discomfort, especially at the edge of the mesh are frequently reported complaints."[26] With the knowledge that the pelvic floor required greater flexibility than the abdominal wall, using this mesh for a transvaginal mesh implant was an avoidable mistake.

A peer-reviewed, published study involving vaginal implantation of three mesh types in rhesus macaques, determined that Gynemesh PS "had the greatest negative impact on vaginal histomorphology and composition," and tissue injury "was highest with Gynemesh PS."[27] This study reports that "[o]ur results showed that following implantation with the stiffer mesh, Gynemesh PS, the vagina demonstrated evidence of a maladaptive remodeling response…. These findings are consistent with our previous study which showed that the tissue mechanical properties of the underlying and associated grafted vagina deteriorated following implantation with the stiffer mesh Gynemesh PS but not the lower stiffness meshes [in the study]. The cause for the tissue degeneration was found to be in large part related to mesh stiffness. In a previous study, we showed that the stiffness of a mesh is intrinsically related to its weight, pore size and porosity. Thus, it is likely that under physiologic loading conditions, a heavier weight, less porous, stiffer mesh will have a more negative impact on the underlying and newly incorporated vagina due to a maladaptive remodeling response induced in part by stress-shielding." This

study directly correlates with information that was known or at least available to Ethicon regarding the negative effects on the pelvic floor tissues of the too-stiff and too-strong Gynemesh PS.

In regards to irritation and infection with Gynemesh PS, its implantation through the transvaginal approach causes the bacteria present in the vagina to attach to the mesh implant, and there is the possibility of proliferation. This can cause inflammation, infection, and fistulae.[28]

As previously discussed, the removal of this mesh implant is challenging, and therefore, can be very distressing and costly to the patient. It appears that the possibility of continuous complications resulting from the implant such as multiple surgeries or the potentially impossible removal of the mesh was never examined by Ethicon. Removal surgery is not always effective; the patient may continue to suffer from complications from the mesh and may still experience pain. As Piet Hinoul, Ethicon's Medical Director, states in a PowerPoint in 2008, "Mesh is permanent. Some complications may require additional surgery that may or may not correct the complication"[29]. Mesh removal itself can be associated with pain, dyspareunia, deformation and abnormal function of vaginal tissues due to the production of excessive scar tissue.

These defects will cause prolapse repair with Gynemesh PS (or Prolene Soft) to fail, as the mesh will shift and migrate, leading to a recurrence of prolapse.

3. Gynemesh PS Implanted Transvaginally for Pelvic Organ Prolapse Repair is Not Superior for Functional Outcomes

Clinical trials have demonstrated that it is erroneous to believe that functional outcomes are better with the use of transvaginally placed mesh like Gynemesh PS. The correct definition of a successful pelvic organ prolapse repair must include both anatomic and functional outcomes.

In fact, "Transvaginal mesh has a higher re-operation rate than native tissue repair" due to the rate of surgeries for attempted repair of complications.[30]

Additionally, it is recognized that the TVM procedure in the posterior compartment does not yield any functional or anatomic benefit.[31] Also, the procedure using mesh results in increased morbidity, mesh extrusion, and higher reoperation rates.[32] A double-blind randomized trial was performed to compare repair of vaginal prolapse with the use of mesh and without the use of mesh. At three years, there was no difference in anatomic benefit between the two, and at three months, there was a 15% mesh exposure rate.[33]

An Ethicon clinical study for transvaginal Gynemesh PS for pelvic organ prolapse repair demonstrated to Ethicon that the mesh was not an effective prolapse treatment (according to Ethicon's own criteria) and presented unreasonable risks. This study, which was performed by physicians who helped develop the Prolift device , had a 75.6% adverse event rate, a "serious" adverse event rate of 25.6%, a 10% "severe" adverse event rate, a 50% rate of adverse event requiring treatment, and a mesh-related adverse event rate of 66.7.[34] Furthermore, the study failed to satisfy Ethicon's own internal criteria for success (defined as a prolapse recurrence rate of less than 20%).[35] Ethicon failed to take any corrective or preventive action based on these study results, and failed to adequately provide any warning or information to physicians about the results of this study. Because the study was conducted to support the clinical safety of the Prolift kit, Ethicon's documents reflect an intent to "differentiate" the study results by pointing out the differences between the TVM procedure with Gynemesh PS and the Prolift kit implantation.[36] This "differentiation" is inappropriate for Prolift, and it certainly does not apply to Gynemesh PS. This study demonstrated that Gynemesh PS was not an effective prolapse treatment, and created risks that were serious and potentially life-altering.

At approximately the same time as the Cosson/Jacquetin study, a separate study was done to evaluate the transvaginal Gynemesh PS in the United States. This study also demonstrated significant complication rates.[37] Specifically, the U.S. study showed that 65.9% of patients suffered at least one adverse event, and that 44.7% of patients suffered an adverse event that was either device-related or procedure-related. [38] The study report also discussed the "success" rates for three groups of patients by the location of the Gynemesh PS implant: anterior repair only; posterior repair only; and both anterior/posterior repair.[39] For both the anterior repair group and anterior/posterior repair group, the study results failed to satisfy Ethicon's own internal criteria for "success."[40] Given that the Cosson/Jacquetin study failed Ethicon's criteria, the results of this study should at a minimum have spurred Ethicon to undertake some sort of corrective action. Ethicon should have warned that the device was a failure for two of the three groups of patients in the U.S. study under Ethicon's own criteria, and further should have warned about the overall complication rates for this study.

In a subsequent study conducted by the same physicians who participated in the development of Prolift and who conducted the earlier Gynemesh PS study, 14% of patients suffered mesh exposure, 19.6% suffered "painful mesh shrinkage," and the objective success rate was only 75.7% after 18 months.[41] These clinical study results further demonstrated that the risks of this product outweighed any potential benefit.

Essentially, there is no supporting evidence that TVM procedure with use of Gynemesh PS provides any benefit in quality of life and many of the complications and risks associated with the surgery have much potential to be more serious and occur more frequently compared to traditional pelvic organ prolapse repair surgeries.

A report based on a critical analysis of literature produced by the French National Authority for Health in 2006 concluded that the literature failed to provide a competent evaluation of the anatomic and functional viability of mesh implants through the vaginal approach in the treatment of pelvic organ prolapse.[42] The report concluded that transvaginal mesh products for the repair of pelvic organ prolapse should be considered a matter of clinical research. They proposed an array of clinical trials to further the investigation into the matter. At this time, Gynemesh PS had been on the market for use in pelvic organ prolapse for 2 years.

In my professional experience, I have read and studied urogynecological articles relevant to the topic at hand. The combination of my personal observations with the removal of Gynemesh PS, the current literature regarding the TVM procedure with mesh implants, the information available on Gynemesh PS and Prolene Soft, and my review of Ethicon's corporate internal documents and testimony, leads me to the opinion that the risks of Gynemesh PS for transvaginal pelvic organ prolapse repair far outweighed any claimed benefits, and the implantation of this product resulted in unacceptable rates of mesh exposures, erosions, dyspareunia, chronic and permanent pelvic pain, painful mesh "shrinkage," stiffness, vaginal deformation, prolapse reoccurrences, and revisions and re-operations in an effort to mitigate these complications. Through personal experience in the treatment of patients who were implanted with Gynemesh PS transvaginally, I have observed such product-related complications as erosion of mesh into the bladder and rectum and exposure of mesh in the vagina; deformed, wrinkled, folded, curled, roped, and fragmented mesh upon removal; rigid scar plate formation, and banding, causing pain; nerve damage or nerve entrapment as a result of mesh scarification and fibrotic bridging; encapsulation of mesh - mesh covered in thick scar; pudendal neuralgia; direct trauma to tissue and nerves that occurred during implantation; infection as a result of the

mesh, including bladder infections, vaginal infections, chronic urinary tract infections, and abscesses; vaginal shortening, tightening, stenosis and/or other deformation of the pelvic anatomy; dyspareunia; vaginal extrusion; pelvic floor muscle spasm; urinary retention; stress urinary incontinence and urge incontinence; constipation or fecal incontinence; chronic or permanent inflammation of tissue surrounding mesh; chronic or permanent pelvic pain; and recurrence of prolapse. These mesh-related complications are consistent with the published medical literature regarding transvaginal repair of pelvic organ prolapse with mesh implants. [43]

In conclusion, my professional opinion to a reasonable degree of medical certainty, which is founded on my education, medical training, personal experience, review of Ethicon materials and testimony, and my knowledge from the published literature regarding the matter, is that the injuries and complications with the Gynemesh PS that I have personally observed, diagnosed, and treated are a direct result of the defective design of this product which I detailed above.

DATA CONSIDERED IN FORMING MY OPINIONS

I considered the documents identified in the body and footnotes of this report, as well as those listed in Exhibit B attached hereto.

EXHIBITS WHICH I PLAN TO USE AS A SUMMARY OF OR IN SUPPORT OF MY OPINIONS

I may use documents that I reviewed and which are identified above, female pelvic floor models and illustrations, samples of Gynemesh PS, and summaries of literature that I may prepare.

COMPENSATION FOR MY REVIEW, STUDY AND TESTIMONY

I charge $1,000 per hour for review and study of records. I charge a 50% premium on records that must be reviewed within 30 days. Deposition fees are $6,000 per half day and $10,000 per full day. Court appearances are $10,000 per day.

OTHER CASES IN WHICH I HAVE TESTIFIED AS AN EXPERT AT TRIAL OR BY DEPOSITION IN THE LAST FOUR YEARS

Linda Fisher, et al. v. Boston Scientific Corporation
Case No. 2:13-cv-29324
United States District Court for the Southern District of West Virginia
11/24/14

Tracy Reynolds v. Boston Scientific Corporation
United States District Court for the Southern District of West Virginia
Case No. 2:12-cv-09934
11/24/14

In re: Boston Scientific Corp. Pelvic Repair System Products Liability Litigation
United States District Court for the Southern District of West Virginia
Wave 1 and 2 Cases
Case No. 2:12-md-02326
1/5/15

Candy Young, et al v. Boston Scientific Corporation
United States District Court for the Southern District of West Virginia
Case No. 2:14-cv-08929
1/24/15

Rae Lynn Herpich, et al. v. C.R. Bard, Inc.
United States District Court for the Southern District of West Virginia
Case No. 2:13-cv-29274
2/10/15

*Chelsea Stewart and Matt Stewart V. Boston Scientific Corp*oration
United States District Court for the Southern District of West Virginia
Case No. 2:12-cv-03686
6/13/15

Candy Young, et al v. Boston Scientific Corporation
United States District Court for the Southern District of West Virginia
Case No. 2:14-cv-08929
1/24/15

Rae Lynn Herpich, et al. v. C.R. Bard, Inc.
United States District Court for the Southern District of West Virginia
Case No. 2:13-cv-29274
2/10/15

*Chelsea Stewart and Matt Stewart V. Boston Scientific Corp*oration
United States District Court for the Southern District of West Virginia
Case No. 2:12-cv-03686
6/13/15

Bobbie Jo Woolf v. Mentor Worldwide LLC
United States District Court for the Middle District of Georgia
Case No. 4:12-cv-00252
9/5/15

Frances McBride v. Mentor Worldwide LLC
United States District Court for the Middle District of Georgia
Case No. 4:12-cv-00249
9/5/15

Dionysios Veronikis, M.D.

[1] ETH.MESH.05455879 (1/18/03 notes from Surgeon Panel Meeting) – "Polypropylene - initial acute inflammation then chronic foreign body reaction….Reaction after 6 years."); ETH.MESH.02017153 (3/06/07 Minutes from an Ethicon Expert Meeting) ("Polypropylene meshes might not be improvable in terms of shrinkage, we may need a completely new material…."); ETH.MESH.00271215 (10/29/08 internal e-mail) – Polypropylene is "the best of a bad lot re integration/retraction" and "there is a need to develop grafts that mimic the human tissue mechanical properties."); ETH.MESH.03722384 (9/17/09 internal e-mail) – "We're seeing a lot of work published that indicates that polypropylene produces an ongoing, chronic inflammatory reaction…Might be better off working with something that is less reactive, like PVDF."); ETH.MESH.01238483 (4/27/09 internal memo) – "Vaginal discomfort is the most troublesome complication of transvaginal mesh and mostly determined by ... Host interaction with the mesh as it relates to chronic inflammation, excessive fibrosis and 'stiffness' from scar plating creating nerve entrapment and or nerve tethering."'); ETH.MESH.05237872 (Nov. 3-4, 2010 "Mesh and Textile Summit") – PowerPoint addressing downsides of "old fashioned" (i.e., polypropylene mesh): "Excessive foreign body reaction; Chronic inflammation; Decreased fibrocollagenous ingrowth; Scar plate formation; Shrinkage from bridging fibrosis.").

[2] ETH.MESH.00680021 (11/12/08 internal e-mail)

[3] ETH.MESH.00870467 ETH.MESH.02017153 (3/06/07 Minutes from an Ethicon Expert Meeting) – "Prof. Cosson questions if Polypropylene is the best material as fractures are observed in pp [sic] after time."); HMESH_ETH_02860031 (7/06/07 internal e-mail from Ethicon Research Fellow regarding "dog" study) – "I recall the long-term dog study did show some 'fibrillation' of PROLENE suture where none was observed for PRONOVA suture. My polymer colleagues tell me that PP has the potential to do this because of its molecular structure."); ETH.MESH.05588123 (7/09/07 internal memo responding to mesh degradation literature) – "There have been a number of anecdotal reports that PP mesh shows some changes in the surface with time. The Aachen group, who has so far collected more than 1000 explanted meshes, showed examples many years back…. We did different tests in-house with accelerated aging, too, and found microscopic changes in the surface of mesh fibres."); ETH.MESH.10578304 (1/18/11 Minutes of PA Consulting Group Meeting regarding Mesh Erosion) – "PP meshes degrade over time following implant; this is observed at very high magnification (using electron microscopy) as 'fractures' in the surface of the extruded fibres which cause particulates of PP to be produced which can break away from the main fibre."); ETH.MESH.14445346 (1/17/12 PowerPoint), Slide 11 (comparing Polypropylene to PVDF) – "PP – Stress cracking after 2 years of implantation [citing Mary article from 1998]… PP – In vivo degradation of PP [citing Clave article from 2009]."); ETH.MESH.07726993 (3/12/12 Ethicon internal memo in response to article reporting polypropylene mesh degradation) – "In an infected field and/or a site of chronic inflammation, it is not unexpected that there will be an increase in free radicals and other reactive oxygen species. Polymers may be subject to surface degradation by these reactive species, the impact of which has not been clinically assessed.").

[4] HMESH_ETH_00228962 (2/17/10 internal e-mail chain discussing literature about polypropylene degradation) – "[W]e know from literature that polyester and even polypropylene

tend to alter over time in the body…. [H]ow has the general surgery group responded to this [degradation literature]?...[W]e proposed for several new product developments...to use PVDF or PRONOVA as a more stable filament, however Senior Management decided to go ahead with PP as a standard." (HMESH_ETH_00228961))

[5] ETH.MESH.12009657 – (4/06/01 internal memo listing disadvantages of Prolene Soft Mesh/Gynemesh PS) – "VOC: too stiff for use in vaginal tissues.")

[6] ETH.MESH.02141727 (5/09/08 internal PowerPoint) – "There is still NO evidence of a Device created specifically for the female pelvis." (p. 4); "Pelvic Floor materials are still over-engineered → we need less foreign body material → materials that correlate to measured female pelvic values." (p. 6)); ETH.MESH.09650760 (11/21/08 invention disclosure) – "Mesh based implants which are currently used in pelvic floor reconstruction are based on mesh constructions originally designed for the treatment of hernias in the abdominal wall region. It is important to understand that the biomechanical properties of the abdominal wall and the pelvic floor differ especially in regard of elasticity and anisotropic material behavior. To fulfil the desired biomechanical compatibility of mesh based implants for pelvic floor reconstruction, it is important to take the biomechanical properties of the implantation site into consideration."); ETH.MESH.02010834 (2/16/11 internal memo "Biomechanical consideration for Pelvic floor mesh design") – p. 2 ("The ideal mesh for prolapse repair which mimics precisely the biomechanical needs of the pelvic floor region has not been developed…. Pain and discomfort can result from stiff mesh that were originally designed for hernia surgery and 'over-engineered' to exceed the burst strength of the abdominal wall at the cost of losing compliance [citing 2009 literature]…. [T]here is significant evidence that the complications associated with synthetic meshes can cause significant morbidity including infection, erosion, exposure, and pain [citing 2000 and 2007 literature]…."); ETH.MESH.08315779 (9/25/12 Ethicon internal report), p. 5782 – "[S]ynthetic mesh implants, even the lower mass mesh implants, are significantly stronger than required.").

[7] ETH.MESH.00877490 (9/8/05 Prolift Poster Presentation by Michel Cosson) "'We can recommend the use of mesh for prolapse surgery, especially patients with big prolapses, and recurrent prolapses,' he said, noting that women with grade 4 prolapse and greater are better suited for mesh surgery than patients with less severe disease.").

[8] ETH.MESH.12873534 (10/25/13 internal e-mail "Poresize for Prolene Soft Mesh") (showing measurements of pores averaging .03, .04, .07, .10, .11, .12, .40, .44, .47, .54 mm^2; the average pore size across all measured pores < 1 mm^2). Not all pores were measured.

[9] HMESH_ETH_00120151 (1/28/13 internal e-mail regarding pore size of Prolene Soft) "[P]ore size measurements vary if the mesh is pulled even lightly in any direction.").

[10] ETH.MESH.03910418 (11/25/02 internal e-mail regarding, inter alia, mesh shrinkage in TVT) – "As we discussed the shrinkage rate is influenced by many parameters as the degree of fibrotic reaction is dependent on the mesh material/weave/width etc. I remember that Axel [Arnaud, Ethicon's European Medical Director] was using 30% shrinkage as a rule of thumb….");

ETH.MESH.00681364 (9/07/04 internal report) – "GYNEMESH PS today has a 'swirling effect' causing what doctors have expressed as 'shrinkage or contraction of the mesh'. It isn't the mesh that's contracting, it's the tissue that seems to be 'bunching' up resulting in the desire to have a more 'tension-free' fixation."); ETH.MESH.05574759 (1/18/05 internal e-mail reporting surgeon's experience with use of Gynemesh in pelvic floor repair) – "a. contraction pulls against the side wall and causes pain b. it causes a hard tissue which can be felt by patient and sexual partner c. it can lead to a balling up of the mesh which is very uncomfortable d. it can lead to suture line dehiscence e. it can lead to prolapse recurrence…. 5) he confirmed our thoughts regarding the correlation between inflammation, foreign body response and scar formation."); ETH.MESH.05246528 (3/10/05 report discussing areas impacting clinical outcomes with mesh) – "Tissue contraction (20-40%), Scar formation = recurrence or dyspareunia…Erosions - potentially address through technique."); ETH.MESH.03915690 (5/13/05 internal memo) – "Although [Gynemesh PS for POP repair] significantly reduces recurrences, as compared to traditional repair, it can lead to other complications such as…mesh retraction…. Mesh retraction ('shrinkage') is a more uncommon complication but it is considered more serious. It can cause a vaginal anatomic distortion, which may eventually have a negative impact on sexual life. Its treatment is difficult."); ETH.MESH.03906579 (6/09/05 interview with Ethicon European Medical Director, Axel Arnaud) – "Shrinkage is due to an excessive scarring process...in a few cases it led to vaginal distortion impacting the sexual life. Thus, the procedure must be used cautiously in sexually active women."); ETH.MESH.05243265 (1/24/06 e-mail discussing meeting with consulting physicians in Europe) – "Their [physicians'] main concern is the believe that the Prolene Soft material over time contracts. Thus creating the potential for failures and/our erosions."); ETH.MESH.03906525 (1/27/06 internal PowerPoint by Ethicon's European Medical Director), Slide 30 ("Mesh must not shrink. Rationale: to preserve the vaginal anatomy and to avoid recurrences. Theory: The scar tissue naturally shrinks up to 70% in the wound area during the healing process. Physiological wound contraction increases with the extent of inflammation. Shrinkage could be minimized by reducing the inflammatory reaction: well tolerated material, large pores."); ETH.MESH.00585938 (2/13/06 internal report on meeting of physician consultants): "The [TVM] group is strongly looking forward to the potential for new materials for the Prolift product. Their main concern is the believe that the Prolene Soft material over time contracts. Thus creating the potential for failures and/our erosions."); ETH.MESH.00870466 (6/2/06 Expert Meeting Memo) ("Shrinkage of 20% means reduction of mesh area to 64%."); ETH.MESH.03160750 (11/15/06 internal e-mail from Ethicon European Medical Affairs Director) – "It came up that there are two issues with Prolift: erosion and shrinkage…The responsibility of the mesh seems to be more established regarding shrinkage…."); ETH.MESH.10511708 (12/12/06 internal R&D PowerPoint "State of Knowledge in Mesh Shrinkage") – "'Shrinking meshes' are a topic of discussion and concern among hernia surgeons. It is believed that mesh shrinkage may lead to patients' discomfort, chronic pain or hernia recurrence…. Mesh shrinkage was evaluated at different time points and the reduction of the calculated area was 12% at one month, 24% at 3 months, 29% at 6 month and 34% at 12 month. [citing 2006 literature]"); ETH.MESH.02017153 (3/06/07 Minutes from an Ethicon Expert Meeting) ("Polypropylene meshes might not be improvable in terms of shrinkage, we may need a completely new material… Unmet clinical needs: No shrinkage/no long term contraction… Severe contraction → Dyspareunia → sexual function ↓."); ETH.MESH.00821702 (9/26/07 internal memo reporting results of 2004 European clinical study of Prolift), Slide 23 –

("Functional results: painful mesh shrinkage. Painful mesh shrinkage (at vaginal examination) – 21 patients (19.6%)…. Correlation between painful mesh shrinkage and dyspareunia but not systematic."); ETH.MESH.01818382 (12/20/07 Ethicon Mesh Contraction preclinical study) (27% shrinkage (measured radiographically) and 23% (measured by image analysis), as well as fibrotic bridging, folding, rippling and distortion, for Prolene Soft in the subcutaneous model after 13 weeks implantation); ETH.MESH.00836975 (3/28/08 internal e-mail from Ethicon Worldwide Medical Director responding to question about how to identify and complications associated with mesh shrinkage) – "First, the mesh doesn't shrink. As collagen grows into the mesh, the entire mass contracts…. In the patient, it can be noted with stiffening of the vaginal wall (causing dyspareunia) or bunching of the Prolift straps (which can cause pain). All patients getting mesh get contraction."); ETH.MESH.01238483 (4/27/09 internal memo) – "Vaginal discomfort is the most troublesome complication of transvaginal mesh and mostly determined by ... Host interaction with the mesh as it relates to chronic inflammation, excessive fibrosis and 'stiffness' from scar plating creating nerve entrapment and or nerve tethering."); ETH.MESH.02227282 (11/14/09 PowerPoint), p. 7 – "Folding of mesh is one cause for erosion and pain."); ETH.MESH.05479695 (Nov. 3-4, 2010 Mesh and Textile Summit PowerPoint) – "There is no place for a 'Heavyweight Mesh' in modern pelvic floor repair… Polypropylene Mesh – Small pore size (<1 mm)… Issues with small pore meshes –…Increased inflammatory response results in rigid scar plate formation – Scar plate responsible for shrinkage of mesh up to 40% [citing published literature from 2002 and 2004].").

[11] ETH.MESH.00584846 (5/10/04 internal e-mail) – "Their [consulting physicians'] main concern is now the shrinkage of the mesh which may lead to pain, dyspareunia…Indeed now that they have tremendously improved the technique and lowered the erosion rate what needs to be improved is the shrinkage of the mesh (in this case gynemesh soft).")

[12] ETH.MESH.04020138 (4/13/05 e-mail from Ethicon engineer) – "In pelvic floor repair even with the PSM, we have seen some scar contracture which translates into procedural complications… [S]urgeons who are our consultants on the ProLift product are asking for a mesh which is better than PSM in this area." (Id.). "The surgeons attribute these conditions [recurrence of prolapse, pain, stiffness, erosion and discomfort during sex] to scar contracture.")

[13] ETH.MESH.00821702 (9/26/07 internal memo reporting results of 2004 European clinical study of Prolift).

[14] ETH.MESH.05455879 (1/18/03 notes from Surgeon Panel Meeting) – "Nerve entrapment with chronic pain - Persistent chronic pain from foreign body reaction – greater fibrosis greater complaints - Scar plate with nerve entrapment - sometimes after one year there are no complaints and then complaints happen – often the result of tiny nerves in the granuloma not just a matter of not damaging the major nerves such as N ilioinguinalis or R genitalis - even if you care for the big nerves you can't prevent pain."); ETH.MESH.00870466 (6/20/06 notes re: Ethicon Expert Meeting) – "Meshes can cause Nerve damage due to mechanical irritation (mesh bears on nerve)…. Vaginal pain after implantation of meshes is rare, but feared, since there is not real treatment option"); HMESH_ETH_01800994 (10/11/06 internal e-mail chain discussing mesh pain/shrinkage literature) ("The take home message from the article was that chronic pain can be associated with placement of a mesh device…. [The author] continues to point out that

neuropathy-related complaints after intraoperative damage of nerve fibers is associated with pain immediately after surgery, however, the onset of chronic pain as a consequence of the 'foreign body reaction' is typically more than one year after the hernia repair. He goes on to point out that patients that reported chronic pain demonstrated nerve fibers and fascicles in the interface of the mesh upon examination upon removal."); ETH.MESH.01238483 (4/27/09 internal memo) – "Vaginal discomfort is the most troublesome complication of transvaginal mesh and mostly determined by ... Host interaction with the mesh as it relates to chronic inflammation, excessive fibrosis and 'stiffness' from scar plating creating nerve entrapment and or nerve tethering.")

[15] ETH.MESH.05479695 (Nov. 3-4, 2010 Mesh and Textile Summit PowerPoint) – "Studies of explanted meshes: • Nerve fibers and fascicles in the interface of mesh • The nerve structures are irritated by the inflammation and cause sensation of pain [citing 2005 article].").

[16] ETH.MESH.01994703 (8/23/07 e-mail chain regarding Lobodasch cadaver lab and clinical experience with Gynemesh PS) ("Yes. Dr. L said he likes that the UP mesh straps are less crumpled and entangled after pullout of the mesh from the cadaver, than the Gynemesh PS. In my own summation, he prefers the UP because it appears to have less memory and not retain creases and bunching upon placement. In our US labs with Dr. Miller, Sepulveda, etc. it was noted by us that upon removal, UP had not reached its elastic limit like PS does (it was not all stretched out at the root of the straps as is seen in Gynemesh PS).").

[17] ETH.MESH.01203957 (11/15/08 PowerPoint slide authored by Piet Hinoul), Slide 8.

[18] ETH.MESH.01771546 (6/28/06 Clinical Study Report), pp. 1550, 1575, 1586-87, 1592 and 1594 (Ethicon Gynemesh PS clinical study showing 65.9% adverse event rate, 44.7% device-related or procedure-related adverse events, and study failed to satisfy Ethicon's success criteria for two of three patient groups – anterior and anterior/posterior – in the study); ETH.MESH.00012009 (6/27/06 Clinical Study Report), p. 12061 and p. 12070 (Ethicon clinical study for Gynemesh PS, showing failure of internal criteria for success, and showing *inter alia* 75.6% complication rate; 25.6% "serious" adverse event rate; 10% "severe" adverse event rate; 50% rate of adverse event requiring treatment; and a mesh-related adverse event rate of 66.7%); ETH.MESH.00821702 (9/26/07 internal memo reporting results of 2004 European clinical study of Prolift: 14% of patients suffered mesh exposure,19.6% suffered "painful mesh shrinkage," and the objective success rate was only 75.7% after only 18 months).

[19] ETH.MESH.05574856 (9/23/03 PowerPoint), Slide 4 ("Pelvic organ prolapse is a <u>functional disorder</u>, not a life threatening disease. 1. Abstention is always a possibility. 2. Whatever the treatment, it must not create serious complications." (Emphasis in original)).

[20] ETH.MESH.00870467 (6/20/06 notes re: Ethicon Expert Meeting) – "Optimum pore size is material dependent (critical pores size; at least 1-2mm), scar formation a combination of pore size, surface area, polymer…. Small pores: interconnection between mesh pores due to fibroses leading to mesh shrinkage…. Tension of the mesh changes pore size → change in elasticity…."); ETH.MESH.01752532 (9/18/06 internal memo) – "Large-pore mesh integrates in a loose network of perifilamentous fibrosis with fat tissue present in between. In contrast, the small-pore mesh incorporates entirely in perifilamentary granulomas and scar tissue, which

bridged the whole pore diameter of less than 1 mm [citing literature from 2002]. It appears that the greater distance between pores resists the ability of 'bridging fibrosis' …, contributing to improved compliance and theoretically less passive compression or shrinkage of the biomaterial…. The applicability of meshes as a prosthesis in the pelvic floor region is dependent on various mesh properties. A suitable mesh should offer a pore size >1mm and feature lightweight properties to avoid the occurrence scar plate formation."); ETH.MESH.10511708 (12/12/06 internal R&D PowerPoint "State of Knowledge in Mesh Shrinkage") – "The tissue incorporation of a mesh prosthesis is proportional to its pore size, since macroporous structures are required for the entrance of macrophages, fibroblasts, blood vessels and collagen fibers. Larger pores allow for faster ingrowth into the mesh, which results in less contraction. On the other hand, the small pore mesh incorporates entirely in perifilamentary granulomas and scar tissue, which bridge the whole pore diameter. This so called 'fibrotic bridging' is a phenomenon that is believed to be closely related to mesh shrinkage and is usually observed in all mesh modifications with pore sizes of less than 1 mm…. Conclusion - the 'ideal mesh': Taking all these abovementioned facts into consideration, the ideal mesh could appear as follows:… pore size > 1mm."); ETH.MESH.01782867 (2/24/07 internal PowerPoint "Factors related to mesh shrinkage"), p. 6 – "Small porous meshes (<1 mm) lead to 'fibrotic bridging' → increased shrinkage…. Pore size – The tissue incorporation of a mesh prosthesis is proportional to its pore size… Larger pores allow for faster ingrowth into the mesh, which results in less contraction. On the other hand, the small pore mesh incorporates entirely in perifilamentary granulomas and scar tissue, which bridge the whole pore diameter. This so called 'fibrotic bridging is a phenomenon that is believed to be closely related to mesh shrinkage and is usually observed in all mesh modifications with pore sizes of less than 1mm."); ETH.MESH.02010834 (2/16/11 internal memo "Biomechanical consideration for Pelvic floor mesh design") – p. 13 ("Lightweight mesh with reduced polypropylene density and larger pore sizes between filaments has shown a pronounced reduction in inflammation and improved integration into surrounding tissue in humans [citing 1999 literature]…. Large-pore mesh integrates in a loose network of perifilamentous fibrosis with fat tissue present in between. In contrast, the small-pore mesh incorporates entirely in perifilamentary granulomas and scar tissue, which bridged the whole pore diameter of less than 1 mm [citing 2002 literature]. It appears that the greater distance between pores resist the ability of 'bridging fibrosis'…, contributing to improved compliance and theoretically less passive compression or shrinkage of the biomaterial."), p. 14 ("[P]ore size is a crucial measure for the safety and efficacy of mesh implants. Whether or not an implant may be exposed to scar plate formation is determined, in part, by the obtained pore size.").

[21] ETH.MESH.02588170 (1/22/08 internal memo regarding desired mesh design features) – "4. shrinkage/stiffening 1. pore size > 3 mm 2. pore size > 1 mm under stretch (mesh + stress shielding component only) • stress shielding of mesh implant (duration < 7d) (Abramov 2006).…Mesh pore size varies under the impact an applied load.")

[22] HMESH_ETH_02860031 (7/06/07 internal e-mail from Ethicon Research Fellow regarding prior "dog" study) – "I recall the long-term dog study did show some 'fibrillation' of PROLENE suture where none was observed for PRONOVA suture. My polymer colleagues tell me that PP has the potential to do this because of its molecular structure."); ETH.MESH.00857704 (2/12/09 internal e-mail regarding development of potential new mesh product constructed of PVDF

"Pronova") – "I think we have multiple advantages over +M like:…If we use PRONOVA a more elastic fiber which show less degradation than PP. Better, longer function of Implant."); HMESH_ETH_00228962 (2/17/10 internal e-mail chain discussing polypropylene literature) – "[W]e know from literature that polyester and even polypropylene tend to alter over time in the body…. [H]ow has the general surgery group responded to this [degradation literature]?...[W]e proposed for several new product developments...to use PVDF or PRONOVA as a more stable filament, however Senior Management decided to go ahead with PP as a standard." (HMESH_ETH_00228961)).

[23] ETH.MESH.02017154 (3/06/07 Minutes from an Ethicon Meeting) "Need to learn more about special anatomic features in vaginal region" and noting that vagina is completely different from abdominal wall.)

[24] ETH.MESH.03904451 (6/06/00 internal memo) – "The in vivo forces and exerted strains on pelvic floor repair during the postoperative period are not known. No studies on this subject were identified through literature search or interviews with experts."); ETH.MESH.05643313 (12/1/00 internal e-mail): "Unfortunately we did not measure the elasticity of endopelvic fascia in our animal studies."); HMESH_ETH_00602957 (8/21/06 internal e-mail) – "There are no data on physical and morphological outcome following vaginal implantation…."); ETH.MESH.02141727 (5/09/08 internal PowerPoint) – "There is still NO evidence of a Device created specifically for the female pelvis." (p. 4); "Pelvic Floor materials are still over-engineered → we need less foreign body material → materials that correlate to measured female pelvic values." (p. 6).); ETH.MESH.02142351 (8/25/08 internal PowerPoint), p. 2 – "[New product design, which never went to market] will be the first PFR device designed specifically for the female pelvis."); ETH.MESH.09650760 (11/21/08 invention disclosure) – "Mesh based implants which are currently used in pelvic floor reconstruction are based on mesh constructions originally designed for the treatment of hernias in the abdominal wall region. It is important to understand that the biomechanical properties of the abdominal wall and the pelvic floor differ especially in regard of elasticity and anisotropic material behaviour. To fulfil the desired biomechanical compatibility of mesh based implants for pelvic floor reconstruction, it is important to take the biomechanical properties of the implantation site into consideration."); ETH.MESH.00751733 (10/22/09 internal PowerPoint), p. 7 – "There is no patient-centric PF material!"; "Different mechanical properties are needed in different area of PF."); ETH.MESH.02227282 (11/14/09 PowerPoint), Slide 3 – Chart showing burst strength of Gynemesh PS is more than 10 times stronger than the maximum intravaginal pressure from physical activity and "Until now, there is no patient-centric POP repair material!! Pelvic Floor Materials are still over-engineered – we need less foreign body material – materials that correlate to measured female pelvic physiological characteristics."); ETH.MESH.08315779 (9/25/12 Ethicon internal report), p. 5782 – "[S]ynthetic mesh implants, even the lower mass mesh implants, are significantly stronger than required.").

[25] ETH.MESH.02010834 (2/16/11 internal memo "Biomechanical consideration for Pelvic floor mesh design") – p. 2 ("The ideal mesh for prolapse repair which mimics precisely the biomechanical needs of the pelvic floor region has not been developed…. Pain and discomfort can result from stiff mesh that were originally designed for hernia surgery and 'over-engineered'

to exceed the burst strength of the abdominal wall at the cost of losing compliance [citing 2009 literature]…. [T]here is significant evidence that the complications associated with synthetic meshes can cause significant morbidity including infection, erosion, exposure, and pain [citing 2000 and 2007 literature]…. In addition, the vaginal tissue to be augmented in often structurally compromised, atrophic, and devascularized…. Moreover, there is evidence that meshes shrink in vivo leading to increased stiffness, pain, and poor restoration of the normal properties of the vagina compliance [citing 2009 literature]. Research has demonstrated that bioprosthetic mesh implantation results in a scarring reaction and subsequent decreased compliance [citing 2009 literature].")

[26]Junge, Elasticity of the anterior abdominal wall and impact for reparation of incisional hernias using mesh implants; Hernia 2001; 5: 113-118.

[27] Liang, et al., Vaginal Degeneration Following Implantation of Synthetic Meshes with Increased Stiffness, BJOG. 2013 January: 120(2):233-243.

[28]Vollebregt, et. al., Bacterial colonization of collagen coated PP vaginal mesh: are additional intraoperative sterility procedures useful? Int. Urogynecol J Pelvic Floor Dysfun. 2009 Nov; 20(11): 1345-51; ETH.MESH.03924600 - (11/10/00 internal memo): "vaginal approach to avoid bacterial environment (the vaginal environment is a notoriously dirty one with abundant bacterial flora; avoidance of bacteria is impossible when employing the vaginal route of application.").

[29] ETH.MESH.01203957 (11/15/08 PowerPoint slide authored by Piet Hinoul), Slide 8.

[30] de Tayrac R et al., Complications of POP Surgery and Methods of Prevention, Int. Urogynecol. J. 2013; 24:1859-1872.

[31] Karram M, Maher C, Surgery for Posterior Wall Prolapse. Int. Urogynecol. J. 2013; 24(11): 1835-41.

[32] Maher C, Anterior Vaginal Compartment Surgery. Int. Urogynocol. J. 2013; 24:1291-1802; Ostergard D, Evidence-based Medicine for Polypropylene Mesh Use Compared with Native Tissue Repair. Urology 79: 12-15, 2012.

[33] Gutman et al., Three-Year Outcomes of Vaginal Mesh for Prolapse. Obstet Gynecol 2013; 122:770-7.

[34] ETH.MESH.00012009 (6/27/06 Clinical Study Report), p. 12061.

[35] ETH.MESH.00012009 (6/27/06 Clinical Study Report), p. 12070.

[36] ETH.MESH.00741137 (6/26/06 memo to Ethicon) – "Prof. Jacquetin's data has not proved as positive as hoped – showing approx 80% success rate – The data will be initially presented at IUGA in September. Note that this data is a retrospective study of over 100 patients using TVM

technique, not necessarily Prolift. This less than 90% success rate forces us to differentiate Prolift from the TVM technique moving forward.").

[37] ETH.MESH.01771546 (6/28/06 Clinical Study Report).

[38] ETH.MESH.01771546 (6/28/06 Clinical Study Report), pp. 1550, 1575, 1586-87, 1592 and 1594.

[39] Id., p. 1588.

[40] Id.

[41] ETH.MESH.00821702 (9/26/07 internal memo reporting results of 2004 European clinical study of Prolift).

[42] French Nat'l Auth. for Health, Dept. of Evaluation of Medical and Surgical Procedures, Nov. 2006.

[43] Hansen, B., et al., *Long-Term Follow-up of Treatment for Synthetic Mesh Complications*, Female Pelvic Med & Reconstr Surg 2014, 20:126-130; Barski D, et al., *Systematic review and classification of complications after anterior, posterior, apical, and total vaginal mesh implantation for prolapse repair.* Surg Technol Int. 2014, 24:217-24.; Shah, et. al., *Mesh complications in female pelvic floor repair surgery and their management: A systematic review*. Indian J Urol. 2012 Apr; 28(2):129-53; Feiner, B., et al., *Vaginal Mesh Contraction: Definition, Clinical Presentation and Management*, Obstet Gynecol 2010, 115:325-330; Morrisoe, S., et al., *The use of mesh in vaginal prolapse repair: do the benefits justify the risks?* Current Opinion in Urology 2010, 20:275-279; Blandon, et al., *Complications from vaginally placed mesh in pelvic reconstructive surgery*, Int Urogynecol J 2009, 20:523-31; Jacquetin, B, *Complications of Vaginal Mesh: Our Experience*, Int Urogyn J, 2009, 20:893-6.

CERTIFICATE OF SERVICE

I hereby certify that on February 1, 2016, I served the **PLAINTIFFS' RULE 26(a)(2)(B) EXPERT REPORT OF DIONYSIOS VERONIKIS, M.D.** on the following counsel of record by electronic mail:

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